Nos. 23-11535-A, 23-11536-A, 23-11537-A,
23-11538-A, 23-11539-A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

IN RE: DEEPWATER HORIZON BELO CASES

BELO PLAINTIFFS, LESTER JENKINS, DWIGHT SIPLES, JR., KENNETH DAVENPORT, and MICHAEL MOULDER,
Plaintiffs-Appellants,

v.

BP EXPLORATION & PRODUCTION, INC., and
BP AMERICA PRODUCTION COMPANY,
Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Florida,
Nos. 3:19-cv-00963, 5:18-cv-00245, 5:19-cv-00012,
5:19-cv-00260, 5:19-cv-00310
Hon. M. Casey Rodgers, United States District Judge

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL

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September 21, 2023

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

A. Pursuant to Eleventh Circuit Rules 26.1-1 through 26.1-3, Amicus Curiae Public Citizen provides the following list of the persons and entities that have or may have an interest in the outcome of this case:

- **Allen, Harley D.**, Plaintiff in *Allen v. BP Exploration & Production, Inc.*, No. 4:19-cv-00008 (N.D. Fla.)
- **Barkley, Shon**, Plaintiff in *Barkley v. BP Exploration & Production, Inc.*, No. 5:19-cv-00048 (N.D. Fla.)
- **Barsanti, Vanessa A.**, Counsel for Defendants-Appellees
- **Beard, Jeffrey**, Plaintiff in *Beard v. BP Exploration & Production, Inc.*, No. 3:19-cv-03224 (N.D. Fla.)
- **Blount, Larry E.**, Plaintiff in *Blount v. BP Exploration & Production, Inc.*, No. 5:19-cv-00227 (N.D. Fla.)
- **Boigris, Dylan**, Counsel for Plaintiffs-Appellants
- **Bourn, Stefan G.**, Counsel for Defendants-Appellees
- **Bowdry, Fabrice**, Plaintiff in *Bowdry v. BP Exploration & Production, Inc.*, No. 5:19-cv-00539 (N.D. Fla.)
- **BP America Production Company**, Defendant-Appellee

- **BP Exploration & Production, Inc.**, Defendant-Appellee
- **BP p.l.c.** (LON: BP; FWB: BPE; NYSE: BP), Corporate Parent of Defendants-Appellees
- **Brannock, Steven L.**, Counsel for Plaintiffs-Appellants
- **Brannock Berman & Seider**, Counsel for Plaintiffs-Appellants
- **Brown, Christopher W.**, Plaintiff in *Brown v. BP Exploration & Production, Inc.*, No. 3:19-cv-00423 (N.D. Fla.)
- **Brown, Jr., Timothy A.**, Plaintiff in *Brown v. BP Exploration & Production, Inc.*, No. 5:19-cv-00369 (N.D. Fla.)
- **Bullock, Lance C.**, Counsel for Defendants-Appellees
- **Cannon, Hope T.**, United States Magistrate Judge
- **Clark, Jason T.**, Counsel for Plaintiffs-Appellants
- **Coleman, Thomas M.**, Plaintiff in *Coleman v. BP Exploration & Production, Inc.*, No. 5:19-cv-00259 (N.D. Fla.)
- **Cook, Shaunette**, Plaintiff in *Cook v. BP Exploration & Production, Inc.*, No. 3:19-cv-03352 (N.D. Fla.)
- **Crowder, Tristian**, Plaintiff in *Crowder v. BP Exploration & Production, Inc.*, No. 5:19-cv-00390 (N.D. Fla.)

- **Crump, Richard M.**, Counsel for Defendants-Appellees
- **Cummings, Tamara M.**, Plaintiff in *Cummings v. BP Exploration & Production, Inc.*, No. 3:19-cv-03042 (N.D. Fla.)
- **Davenport, Kenneth**, Plaintiff-Appellant
- **DeSantis, Karen M.**, Counsel for Defendants-Appellees
- **The Downs Law Group**, Counsel for Plaintiffs-Appellants
- **Durkee, Charles D.**, Counsel for Plaintiffs-Appellants
- **Enger, Ericson W.**, Counsel for Defendants-Appellees
- **Finch, Dallas K.**, Plaintiff in *Finch v. BP Exploration & Production, Inc.*, No. 4:19-cv-00123 (N.D. Fla.)
- **Fountain, Larry**, Plaintiff in *Fountain v. BP Exploration & Production, Inc.*, No. 3:19-cv-03228 (N.D. Fla.)
- **Gerkin, Travis R.**, Plaintiff in *Gerkin v. BP Exploration & Production, Inc.*, No. 5:19-cv-00273 (N.D. Fla.)
- **Gomez Diaz, Jose E.**, Plaintiff in *Gomez Diaz v. BP Exploration & Production, Inc.*, No. 3:19-cv-02112 (N.D. Fla.)
- **Hamilton, Jerry D.**, Counsel for Defendants-Appellees
- **Hamilton, Miller & Birthisel, LLP**, Counsel for Defendants-Appellees

- **Hicks, Jr., George W.**, Counsel for Defendants-Appellees
- **Hinely, Ryan S.**, Plaintiff in *Hinely v. BP Exploration & Production, Inc.*, No. 3:19-cv-03474 (N.D. Fla.)
- **Hodges, Kevin M.**, Counsel for Defendants-Appellees
- **Holley, Devon N.**, Plaintiff in *Holley v. BP Exploration & Production, Inc.*, No. 5:19-cv-00343 (N.D. Fla.)
- **Hunton Andrews Kurth LLP**, Counsel for Defendants-Appellees
- **Jagadich, Adam J.**, Counsel for Defendants-Appellees
- **Jakola, Adrianne K.**, Counsel for Defendants-Appellees
- **Jarrett, R. Keith**, Counsel for Defendants-Appellees
- **Jenkins, Lester**, Plaintiff-Appellant
- **Johnson-Barnes, Zebulun**, Plaintiff in *Johnson-Barnes v. BP Exploration & Production, Inc.*, No. 5:19-cv-00391 (N.D. Fla.)
- **Jones, Christi G.**, Counsel for Defendants-Appellees
- **Jones, Gary R.**, United States Magistrate Judge
- **Kennedy, Jessica M.**, Counsel for Defendants-Appellees
- **King, Courtney M.,** Counsel for Defendants-Appellees

- **Kirkland, Luther H.**, Plaintiff in *Kirkland v. BP Exploration & Production, Inc.*, No. 5:19-cv-00462 (N.D. Fla.)
- **Kirkland & Ellis LLP**, Counsel for Defendants-Appellees
- **Larey, Jason M.**, Counsel for Plaintiffs-Appellants
- **Liskow & Lewis**, Counsel for Defendants-Appellees
- **Long, Sarah A.**, Counsel for Defendants-Appellees
- **Lowery, Daniel**, Plaintiff in *Lowery v. BP Exploration & Production, Inc.*, No. 3:20-cv-03646 (N.D. Fla.)
- **Mancini, Sara M.**, Counsel for Plaintiffs-Appellants
- **Marengo, Jose D.**, Plaintiff in *Marengo v. BP Exploration & Production, Inc.*, No. 3:19-cv-00007 (N.D. Fla.)
- **Maron Marvel Bradley Anderson & Tardy LLC**, Counsel for Defendants-Appellees
- **McCoy, Kalleigh A.**, Counsel for Defendants-Appellees
- **McDonald, Jr., Francis M.**, Counsel for Defendants-Appellees
- **McDonald Toole Wiggins, P.A.**, Counsel for Defendants-Appellees

- **McEldowney, Catherine P.**, Counsel for Defendants-Appellees
- **McLeod, Jr., Chan**, Counsel for Defendants-Appellees
- **McLoone, Jennifer A.**, Counsel for Defendants-Appellees
- **McNeal, Robert B.**, Counsel for Defendants-Appellees
- **Moulder, Michael**, Plaintiff-Appellant
- **Moxon, Shea**, Counsel for Plaintiffs-Appellants
- **Nakoa, Jamie K.**, Counsel for Defendants-Appellees
- **Nielson, Aaron L.**, Counsel for Defendants-Appellees
- **Public Citizen**, Amicus Curiae
- **Reid, Devin C.**, Counsel for Defendants-Appellees
- **Rivers, Edna Mae**, Plaintiff in *Rivers v. BP Exploration & Production, Inc.*, No. 3:20-cv-00029 (N.D. Fla.)
- **Rodgers, M. Casey**, United States District Judge
- **Roth, Martin L.**, Counsel for Defendants-Appellees
- **Sansone, Nicolas A.**, Counsel for Amicus Curiae Public Citizen
- **Sastre, I, Hildy M.**, Counsel for Defendants-Appellees
- **Seiler, Scott C.**, Counsel for Defendants-Appellees

- **Shook, Hardy & Bacon L.L.P.**, Counsel for Defendants-Appellees
- **Silverman, Bradley A.**, Counsel for Defendants-Appellees
- **Simon, Nicholas D.**, Counsel for Defendants-Appellees
- **Siples, Jr., Dwight**, Plaintiff-Appellant
- **Smith, Schuyler A.**, Counsel for Defendants-Appellees
- **Smith, Stephanie M.**, Counsel for Defendants-Appellees
- **Sostre, Hector**, Plaintiff in *Sostre v. BP Exploration & Production, Inc.*, No. 3:19-cv-03608 (N.D. Fla.)
- **Tardy, III, Thomas W.**, Counsel for Defendants-Appellees
- **Taylor, Thomas W.**, Counsel for Defendants-Appellees
- **Toles, Andre**, Plaintiff in *Toles v. BP Exploration & Production, Inc.*, No. 3:21-cv-03028 (N.D. Fla.)
- **Van Giesbrecht, Johnney**, Plaintiff in *Van Giesbrecht v. BP Exploration & Production, Inc.*, No. 3:19-cv-00074 (N.D. Fla.)
- **Virden, Cecelia**, Counsel for Defendants-Appellees
- **Williams & Connolly LLP**, Counsel for Defendants-Appellees
- **Wilmore, Charles B.**, Counsel for Defendants-Appellees

- **Wilson Elser LLP**, Counsel for Defendants-Appellees
- **Woods, Jason E.**, Plaintiff in *Woods v. BP Exploration & Production, Inc.*, No. 5:19-cv-00200 (N.D. Fla.)
- **Zieve, Allison M.**, Counsel for Amicus Curiae Public Citizen

B. Amicus curiae Public Citizen is a nonprofit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

Respectfully submitted,

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September 21, 2023

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INTEREST OF AMICUS CURIAE[1]

Public Citizen is a nonprofit consumer advocacy organization with members in all fifty states. Public Citizen works before Congress, administrative agencies, and courts to advance the interests of consumers, workers, and the public. Public Citizen has a longstanding interest in promoting legal rules that more effectively enable workers and other members of the public to seek redress when corporate practices expose them to health or environmental hazards, and it regularly files briefs in the Supreme Court and the courts of appeals advocating for such rules. *See, e.g.*, *Atl. Richfield Co. v. Christian*, 140 S. Ct. 1335 (2020); *CTS Corp. v. Waldburger*, 573 U.S. 1 (2014); *Palmer v. Amazon.com, Inc.*, 51 F.4th 491 (2d Cir. 2022). Moreover, Public Citizen holds a particular interest in this litigation in light of Public Citizen's consistent efforts to ensure that Defendants-Appellees BP Exploration & Production, Inc., and BP America Production Company (together, BP), and their corporate affiliates, are held accountable for their role in the Deepwater Horizon

[1] This brief was not authored in whole or part by counsel for a party, and no one other than amicus curiae or its counsel made a monetary contribution to the preparation or submission of the brief. Counsel for all parties have consented to its filing.

explosion and oil spill that allegedly gave rise to the adverse health conditions of Plaintiffs-Appellants (Plaintiffs). *See, e.g.*, Memorandum of Amicus Curiae Public Citizen, *BP Exploration & Prod., Inc. v. McCarthy*, No. 4:13-cv-2349 (S.D. Tex. Feb. 4, 2014), https://tinyurl.com/mrer4p4y; Robert Weissman, *Boycott BP* (May 24, 2010) (calling for a three-month boycott of BP, in part because of BP's "hedg[ing]" over whether it would "pay for the harms caused by the spill"), https://tinyurl.com/yxxs8fm7.

STATEMENT OF THE ISSUE

Whether the district court abused its discretion in excluding the general-causation opinions of Plaintiffs' experts on reliability grounds.

SUMMARY OF ARGUMENT

I. The Federal Rules of Evidence take a liberal approach to admissibility, establishing a baseline rule that juries are presumptively entitled to consider relevant evidence. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court held that Rule 702, which governs the admissibility of expert opinions, reflects this liberal approach. Rule 702, *Daubert* held, displaces earlier common-law admissibility restrictions and empowers juries to hear even "shaky" expert evidence that nonetheless derives from reliable methodologies.

While Rule 702 thus broadens the range of expert opinions to which juries may be exposed, the *Daubert* Court voiced confidence that the adversarial process will properly equip juries to make the ultimate determination on whether to credit or reject a particular expert's opinion.

II. Experts seeking to determine whether a particular substance has adverse health effects cannot ethically conduct controlled clinical studies on humans, but at least two principal methodologies can offer reliable inferential support for a causal link. First, observational epidemiology involves identifying real-world populations that have been exposed to the substance and comparing them to unexposed populations. If the comparison reveals an association between exposure and a given health condition, an expert can make a scientific judgment based on a variety of factors as to whether the association is likely causal. Second, toxicology involves exposing laboratory animals to varying doses of a substance and observing the results. Given the difficulties of using a substance's impact on animals under laboratory conditions to infer its impact on humans under real-world conditions, however, this Court has identified epidemiology as the more reliable methodology. That said, a single epidemiological study rarely provides a sufficiently clear picture to

support a confident conclusion on causation. To make a reliable causal inference, an expert typically examines the entire body of relevant studies, assesses whether the studies cohere with one another and with accepted scientific background principles, and draws a conclusion based on the overall weight of the evidence.

III. In excluding Plaintiffs' experts' general-causation opinions as unreliable, the district court adopted a report and recommendation (R&R) that applied reliability standards that are untethered from the standard epidemiological methodology that Plaintiffs' experts employed.

A. Throughout, the R&R flyspecked the epidemiological studies on which Plaintiffs' experts relied, identifying ways that individual studies fell short of conclusively establishing a causal link. But observational studies are necessarily constrained by real-world conditions, which is why the experts—consistent with standard practice—based their opinions as to causation on an internally consistent *body* of studies that lined up with existing scientific knowledge, rather than treating any single study as dispositive. For all the R&R's granular analysis, it failed to ask whether the studies could reliably serve the purpose for which the experts actually used them: to act as mutually reinforcing components of

a coherent scientific narrative suggesting a likelihood that exposure to crude oil and chemical dispersants can damage the sinuses.

B. The R&R repeatedly misapplied epidemiological methodology in other ways, too. It required Plaintiffs' experts to identify a threshold dose at which exposure would be harmless, even though this inquiry has little to do with general causation and, in any event, falls within the province of toxicology, not epidemiology. It similarly conflated methodologies by requiring the experts to demonstrate a relationship between dose and the severity of a biological response, even though epidemiological studies (unlike toxicological studies) are rarely designed to explore such relationships. It faulted the experts for failing to consider the background risk of the sinus conditions at issue, even though epidemiological studies by their very design account for background risk. And it required the experts to isolate a specific chemical that is capable of producing Plaintiffs' health conditions, even though epidemiology studies the effect of substances as they are found in the real world and not in a laboratory.

ARGUMENT

I. Rule 702 favors the admission of expert opinions that are based on reliable methodologies and leaves it to juries to decide whether the opinions are ultimately persuasive.

In 1975, Congress displaced the common-law rules of evidence that had previously applied in federal courts by enacting a comprehensive statutory framework derived from a set of proposed rules initially created by a judicial advisory committee. An Act to Establish Rules of Evidence for Certain Courts and Proceedings, Pub. L. No. 93-595, 88 Stat. 1926; *see* H.R. Rep. 93-650, at 7076–77 (1975). The Federal Rules of Evidence, as legislatively enacted, took a "liberal thrust" on issues of admissibility, *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988), creating a baseline rule that all relevant evidence, broadly defined, is admissible in federal court, absent a conflict with other specified sources of federal law. Fed. R. Evid. 402; *see* Fed. R. Evid. 401 (defining relevant evidence as that which has "any tendency" to "to make a fact more or less probable").

Among the Rules' liberalizing features was their "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp.*, 488 U.S. at 169. Rule 704, for example, "specifically abolished" the common-law prohibition on opinion testimony addressing "ultimate"

issues. Fed. R. Evid. 704 advisory committee's note. Meanwhile, Rule 703 "broaden[ed]" the sorts of facts or data that could permissibly form the basis for an expert's opinion "beyond [those which were then] current in many jurisdictions," in an attempt to "bring the judicial practice into line with the practice of the experts themselves when not in court." Fed. R. Evid. 703 advisory committee's note.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court construed Rule 702's standard for admitting expert testimony against this "permissive backdrop." *Id.* at 589. Prior to the Rules' enactment, the "dominant standard for determining the admissibility of novel scientific evidence"—derived from *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)—held scientific evidence inadmissible unless it employed methodologies "sufficiently established to have gained general acceptance" in the relevant field. *Daubert*, 509 U.S. at 585–86 (second quoting *Frye*, 293 F. at 1014; emphasis omitted). But Rule 702, as initially enacted, broadly authorized qualified experts to testify to their "scientific, technical, or other specialized knowledge … in the form of an opinion or otherwise," as long as the testimony would "assist the trier of fact to understand the evidence or to determine a fact

in issue." Fed. R. Evid. 702 (1975). *Frye*'s "rigid 'general acceptance' requirement," *Daubert* held, had no basis in the Rule's text and was "at odds with the 'liberal thrust' of the Federal Rules" more generally. 509 U.S. at 588 (quoting *Beech Aircraft Corp.*, 488 U.S. at 169).

At the same time, *Daubert* noted that the Rules' displacement of the *Frye* standard "d[id] not mean … that the Rules themselves place no limits on the admissibility of purportedly scientific evidence." *Id.* at 589. Rather, *Daubert* explained, Rule 702 contemplated a role for the trial court in "ensur[ing] that any and all scientific testimony or evidence admitted is not only relevant, but reliable," *id.*, and so guarding against the presentation of "absurd and irrational pseudoscientific assertions" to the jury, *id.* at 595. Critically, though, because "there are no certainties in science," a field in which hypotheses are tested and refined over time, *Daubert* held that mere doubt over the validity of an expert's conclusions is insufficient to render the expert's opinion unreliable and, therefore, inadmissible. *Id.* at 590. A trial court's focus, rather, must be on "whether the *reasoning* or *methodology* underlying [an expert's] testimony is scientifically valid." *Id.* at 592–93 (emphases added). The Court recognized that lifting the common-law prohibition on expert opinions

that are based on methodologies that have not yet gained general acceptance might expose juries to "shaky but admissible" testimony. *Id.* at 596. But the "appropriate means of attacking" such testimony, the Court explained, is "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof," not "wholesale exclusion." *Id.*

Following *Daubert*, the Rules advisory committee amended Rule 702 to incorporate the decision's reliability standard into the Rule's text. *See* Fed. R. Evid. 702 advisory committee's note on 2000 amendment. In doing so, the committee emphasized that "the rejection of expert testimony is the exception rather than the rule" and that "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." *Id.* (second quoting *United States v. 14.38 Acres of Land*, 80 F.3d 1074, 1078 (5th Cir. 1996) (per curiam)). And although a trial court enjoys a level of discretion in assessing the reliability of proffered expert evidence under Rule 702, "[c]ourts have found that an abuse of discretion occurs when under *Daubert* the admissibility bar is too high." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1321 (11th Cir. 1999) (citing *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77,

85 (1st Cir. 1998)); *see, e.g.*, *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1355 (11th Cir. 2014) (per curiam) (holding that the district court abused its discretion in excluding expert evidence based on "asserted problems" that "could be addressed through the conventional adversarial means and assessed by the jury"); *14.38 Acres of Land*, 80 F.3d at 1079 (reversing the exclusion of expert evidence because "[t]he perceived flaws" in the evidence were "matters properly to be tested in the crucible of adversarial proceedings," not a "basis for truncating that process").

II. Drawing a causal inference from a body of epidemiological studies that would each independently be insufficient to support the inference can be a reliable methodology.

The "gold standard" methodology for drawing a scientific conclusion about the effect that a particular substance has on human health is a controlled study that exposes one group of people to the substance and compares outcomes for that group to outcomes for a similarly constituted control group that has not been exposed to the substance. Michael D. Green, et al., *Reference Guide on Epidemiology* (hereinafter, *Ref. Guide Epidem.*), *in* Fed. Jud. Ctr., Nat'l Research Council of the Nat'l Acads., *Reference Manual on Scientific Evidence* 549, 555 (3d ed. 2011), https://tinyurl.com/r373cjjt (hereinafter, *Ref. Manual*). Researchers evaluating

whether a new drug is safe and effective for use in humans, for example, undertake controlled clinical trials to compare outcomes for patients to whom the drug is administered and patients to whom it is not—after conducting preliminary laboratory and animal tests to ensure that the clinical trials will not expose the human participants to the risk of harm. *See* U.S. Food & Drug Admin. (FDA), *Step 3: Clinical Research* (Jan. 4, 2018), https://tinyurl.com/yttstres. Researchers evaluating a causal link between a particular substance and an *adverse* health condition, however, are precluded by ethical standards from conducting studies that would deliberately expose human subjects to the substance. *Ref. Guide Epidem.* at 555 & n.15. They accordingly often must instead draw inferences from observational epidemiological studies and/or toxicological studies. *See id.* at 556–65.

In observational epidemiological studies, a researcher does not control a preselected population's exposure to the potentially harmful substance under laboratory conditions but instead studies a group of individuals who have been exposed to the substance during the course of real-world events and compares that group to an unexposed group. *Id.* at 555–56. Because these studies usually "focus on individuals living in the

[relevant] community," a researcher cannot control the characteristics of the individuals involved. *Id.* at 556. But a well-designed study that accounts for "the possibility of differences in the two populations being studied with regard to risk factors other than exposure" can provide reliable (although not definitive) information about whether exposure is associated with an observed health outcome and about the strength of any association. *Id.* at 556–57. Of course, the possibility always exists that an association observed in a given study is the product of random chance, *id.* at 573, and researchers use the term "statistically significant" to indicate that "the probability … of observing an association at least as large as that found in the study when in truth there is no association" falls below a predetermined level (often 5%) called a *p*-value, *id.* at 576–77. That said, "any criterion for 'significance' is somewhat arbitrary," *id.* at 573, and even findings of a very strong association with a very high probability of being "true" (up to just shy of 95%, for example, where the *p*-value is 5%) can technically be deemed statistically insignificant.

Once an observational study has revealed an association between exposure to a substance and a particular health condition, a researcher must next assess the likelihood that the substance is a *cause* of the

condition—in other words, the likelihood that the increased incidence of the condition among exposed individuals would not have been observed but for the fact of exposure. *Id.* at 597–98. An inference of causation, while "informed by scientific expertise," cannot be "made by using an objective or algorithmic methodology" and instead depends on a researcher's "judgment." *Id.* at 600. A set of nine factors known as the Hill factors can guide epidemiologists in making causal inferences by prompting them to consider, for example, the temporal relationship between the exposure and the health outcome, the strength of the association between exposure and the risk of experiencing the outcome, and whether a causal relationship would cohere with existing knowledge about biological structures and processes. *Id.* at 599–600. But "no formula or algorithm … can be used to assess whether a causal inference is appropriate" based on the factors, and "there is no threshold number" of factors that must be met before such an inference can be drawn. *Id.*

The other methodology that researchers commonly use to assess the relationship between a particular substance and a particular adverse health condition is toxicology (or a "dose-response" methodology, as the

R&R termed it, *see* D. Ct. Dkt. No. 570 (R&R) at 13–14[2]), which typically involves testing the substance on laboratory animals at varying dosages.[3] *Ref. Guide Epidem.* at 563. Toxicological studies are useful in assessing causation because they "can be conducted as true experiments," as "researchers control all aspects of the animals' lives." *Id.* But they have "two significant disadvantages." *Id.* First, anatomical differences between humans and other animals mean that an observed effect in an exposed laboratory animal will not necessarily occur, or occur in the same way, in a similarly exposed human. *Id.* Second, because animal studies often involve exposure at high doses, even studies that suggest a causal link between a substance and a health effect may leave open the possibility that real-world human exposures would fall below a lower "threshold no-effect dose" and so not be associated with any adverse health consequences. *Id.*

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[2] Consistent with Plaintiffs' opening brief, citations to the district court docket refer to the docket in Case No. 3:19-cv-00963 (N.D. Fla.).

[3] The R&R referred to "background risk" as a third methodology for assessing causation. R&R at 14–15. As discussed *infra* at 26–28, however, controlling for the background risk of contracting a given health condition from a source other than exposure to the substance being studied is an aspect of epidemiological study design, not a distinct methodology.

This Court has recognized that "[e]pidemiology … is generally considered to be the best evidence of causation in toxic tort actions." *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1198 (11th Cir. 2002); *see also, e.g.*, *Allison*, 184 F.3d at 1314 (faulting an expert for failing to explain "why the results of … animal studies should trump more than twenty … epidemiological studies"). But "a single [epidemiological] study" will "[r]arely, if ever, … persuasively demonstrate a cause-effect relationship." *Ref. Guide Epidem.* at 604. Drawing a reliable causal conclusion instead "typically requires consideration of numerous findings, which, when considered alone, may not individually prove the [conclusion]." Margaret A. Berger, *The Admissibility of Expert Testimony*, *in Ref. Manual* 11 at 19–20. Accordingly, "many of the most well-respected and prestigious scientific bodies … consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence." *Id.* at 20 (citing sources).

The First Circuit expressly recognized this point in a decision reversing the exclusion of an expert opinion that was based on the aggregate weight of admittedly imperfect evidence. As that court

explained, scientists tasked with drawing causal inferences can reliably "reason[ ] to the best explanation for all of the available evidence," even if no one body of evidence "itself … justif[ies] an inference of causation." *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 23 (1st Cir. 2011). Where "no one line of evidence support[s] a reliable inference of causation," it does not follow that "an inference of causation based on the totality of the evidence [is] unreliable." *Id.*

III. The district court abused its discretion in excluding the opinions of Plaintiffs' experts as insufficiently reliable to present to a jury.

The district court based its decision to exclude the expert opinions of Dr. Gina Soloman and Dr. Michael Freeman as unreliable on an R&R that repeatedly misconstrued the standards of the epidemiological methodology that these experts employed. *See* D. Ct. Dkt. No. 591 (D. Ct. Op.) at 12 (adopting the R&R in full).[4] First, the R&R critiqued specific

[4] The district court also excluded the opinions of Dr. David Carpenter and Dr. Ranajit Sahu. D. Ct. Op. at 12. Dr. Carpenter's opinion was limited to ocular conditions, *see* R&R at 36, and this brief does not address the opinion because the Plaintiffs for whom it was relevant have moved to dismiss their appeal, *see* Opening Br. 3. As for Dr. Sahu, his opinion was challenged and excluded on helpfulness grounds alone, D. Ct. Op. at 6 n.7, and so the decision to exclude his opinion falls outside the scope of this brief's discussion of reliability.

studies that the experts cited without acknowledging that the experts—consistent with standard practice, *see supra* at 15–16—based their causal conclusions on an aggregate body of evidence, of which each individual study formed only a single, necessarily imperfect component. Second, the R&R repeatedly faulted the experts for failing to comply with requirements—many drawn from the distinct field of toxicology—that have no foundation in epidemiological practice.

A. The district court failed to appreciate that the experts relied on the *cumulative* force of a body of studies that cohere with existing knowledge about how exposure to crude oil and dispersants can affect the body.

1. Employing the standard epidemiological methodology described above, Plaintiffs' experts examined a range of studies of varying quality and persuasive force and made probabilistic judgments on causation after considering the cumulative weight of the studies against the backdrop of existing scientific knowledge.

Dr. Solomon began her report with an explanation of the physical process by which inhalation of the chemicals and particulate matter found in crude oil and dispersants can damage the biological structures of the upper respiratory tract, including the sinuses. D. Ct. Dkt. No. 466-1

(Solomon Rep.) at 8–12.[5] After explaining how the Deepwater Horizon clean-up workers inhaled these substances, she described a series of epidemiological studies that, to varying extents, suggested an association between the inhalation of crude oil or dispersants and respiratory or sinus conditions. *Id.* at 12–16. While accepting that "[t]he evidence quality overall [was] moderate," Dr. Solomon observed that "[t]he evidence that does exist is coherent, with multiple threads of evidence all pointing to a common conclusion," and she ultimately found "sufficient scientific evidence to infer general causation with a moderate-to-high level of confidence." *Id.* at 17; *see also, e.g.*, *id.* at 14 (explaining that a study in which forty out of forty-four participating Deepwater Horizon clean-up workers developed chronic sinusitis over a seven-year period "support[ed] what would be expected to occur based on the properties of the oil-dispersant aerosols" the workers encountered, "the physiology of the upper respiratory tract, and the toxicity of the petroleum and dispersant chemicals to the cells and tissues of the nasopharynx").

[5] Dr. Solomon prepared two expert reports, *see* D. Ct. Dkt. Nos. 466-1, 466-2, but because the two reports are identical in all relevant respects, this brief follows Plaintiffs' opening brief in citing and referring only to the report Dr. Solomon wrote for Plaintiff-Appellant Lester Jenkins, *see* Opening Br. 6.

Dr. Freeman's sinusitis report took a similar approach. Even before turning to the scientific evidence, he made the "common-sense" point that "[i]t is not difficult to understand, from common experience, that an inhaled chemical irritant can cause inflammation of the nasal sinuses resulting in acute illness, and that in some cases, the acute illness can persist and become chronic." D. Ct. Dkt. No. 469-1 at 8 (emphasis omitted). He then described the physical effects that irritants can have on the sinuses, *id.* at 12, and identified chemicals contained in crude oil and dispersants that are known to be "respiratory irritants," *id.* at 13. Only after laying this groundwork did Dr. Freeman examine several epidemiological studies that showed an association between exposure to crude oil or dispersants and sinusitis. *Id.* at 13–21. Emphasizing that the body of epidemiological evidence painted an internally consistent and "biologically plausible" picture that cohered with available toxicological studies and common sense, Dr. Freeman concluded that occupational exposure to the crude oil and dispersants associated with the Deepwater Horizon spill increased the risk of chronic sinusitis by at least 55%. *Id.* at 21–23.

To be sure, Plaintiffs' experts based their opinions on inferences drawn from a collection of sources that did not purport to establish a definitive causal link between exposure to a given substance and a given health outcome. As Dr. Solomon explained, the "double-blind randomized trials in humans" that could, in theory, offer something closer to "[c]onclusive proof of disease causation" would be "unethical and illegal." Solomon Rep. at 6–7; *see Ref. Guide Epidem.* at 555. But as this Court has observed, "a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists." *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 745 (11th Cir. 1986) (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1535 (D.C. Cir. 1984)). After all, assessing causation requires an expert to exercise "judgment about how the [relevant] study findings fit with other scientific knowledge." *Ref. Guide Epidem.* at 553. Qualified experts might reach different inferential conclusions even after faithfully applying established principles. Under *Daubert*, it is for the jury to decide which conclusion is most persuasive.

2. Missing the forest for the trees, the R&R repeatedly discounted the probative value of the observational studies on which Plaintiffs'

experts relied or distinguished the studies' factual circumstances from the circumstances here. R&R at 25–32, 56–64. As Plaintiffs explain in their brief, Opening Br. 26–35, 40–46, 51–54, the R&R's criticisms are largely misguided. More fundamentally, though, the R&R disregarded that the experts drew their opinions from a *body* of observational studies that, when taken in the aggregate and viewed together with established biological principles, supported a reasonable inference that exposure to crude oil and dispersants can cause sinus conditions.

Certainly, a jury would be entitled to doubt the validity of the experts' conclusions after "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Daubert*, 509 U.S. at 596. The focus at the admissibility stage, though, "must be solely on principles and methodology." *Id.* at 595. Yet the R&R never explains why the experts' reliance on a broadly consistent body of studies that cohere with existing knowledge about human anatomy departed so far from reliable scientific practice as to foreclose a jury from hearing the experts' opinions, even if each individual study may well be susceptible to the sort of critique BP would be free to offer at trial.

B. The district court imposed requirements that have no basis in standard epidemiological methodology.

While the district court's failure to appreciate the cumulative basis for the opinions of Plaintiffs' experts was itself an abuse of discretion that requires reversal, the district court also abused its discretion by faulting Plaintiffs' experts for failing to satisfy at least four requirements that have no foundation in the epidemiological methodology they employed.

1. The R&R that the district court adopted faulted each expert's opinion for failing to identify a threshold dose at which exposure to crude oil and dispersant becomes harmful. R&R at 15–20, 22–24, 55. General causation, however, presents only "the 'general issue of whether a substance has the potential to cause the plaintiff's injury.'" *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1306 (11th Cir. 2014) (quoting *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1248 n.1 (11th Cir. 2010) (per curiam)). Where an epidemiological study demonstrates an observed association between a real-world exposure to the substance and human health, an expert can reliably resolve that issue in the affirmative, irrespective of whether some *other*, lower-level exposure might *not* trigger the health consequence at issue.

Threshold dose can be relevant to *specific* causation—that is, whether the substance at issue is responsible for a particular plaintiff's injury. *See Chapman*, 766 F.3d at 1303. After all, for a jury to find that a specific exposure caused a plaintiff's health condition, there must be a basis for concluding that the plaintiff's specific degree of exposure could have produced the condition. The distinct general-causation inquiry, though, asks whether *any* exposure level could have done so. *See* Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology* (hereinafter, *Ref. Guide Toxic.*), *in Ref. Manual* 633 at 638 (contrasting specific causation, where "the primary issue will be whether there has been exposure to a sufficient dose to be a likely cause of th[e] effect," with general causation, where dose is "not … a central issue").

This Court's decision in *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005), does not support the R&R's requirement that a plaintiff establish threshold dose at the general-causation stage. The R&R cited *McClain* for the proposition that "'scientific knowledge of the harmful level of exposure to a chemical' is … 'necessary to sustain the plaintiff's burden.'" R&R at 15 (quoting *McClain*, 401 F.3d at 1241). But the expert in *McClain* based his opinion on "principles of pharmacology,"

401 F.3d at 1242, *not* epidemiology, *see id.* at 1251.[6] And contrary to the R&R's view, R&R at 16 n.11, this distinction makes a difference. Whereas pharmacological tests showing that a substance is harmful to animals (or beneficial to humans) when administered at carefully calibrated doses in a clinical setting leave open the possibility that real-world exposure levels are not harmful to humans, *see supra* at 14, epidemiological studies foreclose that possibility by establishing an observed association between actual human exposures and an adverse health impact.

2. The R&R similarly conflated methodologies when it faulted Plaintiffs' experts for failing to establish that "a change in amount, intensity, or duration of exposure" to crude oil or dispersants was "associated with a change—either an increase or decrease—in risk of disease." R&R at 33 (quoting *McClain*, 401 F.3d at 1241–42); *see id.* at 33–34. The existence of this sort of dose-response relationship is one of

[6] Pharmacology and toxicology are "related fields," *Ref. Guide Toxic.* at 636, and both involve testing substances on animals to determine their biological effects, *see United States v. Way*, 2018 WL 5310773, at *4 (E.D. Cal. Oct. 25, 2018). But because pharmacology, unlike toxicology, usually asks whether a potentially beneficial drug can be *safe* for human consumption, *see id.*, researchers can ethically conduct controlled human trials under certain circumstances. *Cf.* FDA, *Conducting Clinical Trials* (June 30, 2020), https://tinyurl.com/52up7djk.

the Hill factors and can *support* a causal inference under an epidemiological approach. *Ref. Guide Epidem.* at 603. It is, however, "not essential" to a reliable inference. *Id.* Many epidemiological studies "do not have direct information about dose," *Ref. Guide Toxic.* at 658, and "some causal agents do not exhibit a dose-response relationship" under certain real-world conditions, *Ref. Guide Epidem*. at 603.

The undue significance that the R&R assigned to the dose-response relationship rested, again, on a misapplication of *McClain*, which stated that "[a] court should pay careful attention to [an] expert's testimony about the dose-response relationship" and that "neglect[ing]" the relationship "casts suspicion on the reliability of [the expert's] methodology." 401 F.3d at 1241–42. Here too, though, *McClain* addressed *pharmacological* methodology, which, like toxicology, involves laboratory experiments designed "to determine the dose-response relationships of a compound by measuring how response varies with dose." *Ref. Guide Toxic.* at 641; *see supra* at 24 n.6 (explaining that pharmacology and toxicology are methodologically related). Observational epidemiological studies, in contrast, do not replicate laboratory conditions and so do not

generally permit—let alone require—systematic examination of the effects that varying dosages have on biological processes.

3. The R&R further misconstrued the practice of epidemiology when it faulted Plaintiffs' experts for failing to account explicitly for the background risk of Plaintiffs' health conditions. R&R at 35–36. An epidemiological study automatically accounts for background risk by comparing otherwise similar populations of exposed and unexposed individuals; both the exposed and the unexposed groups are subject to the same background risk, so increased incidence of a health condition within the exposed group cannot be attributed to background risk.[7]

Here too, the R&R derived its novel methodological requirement from this Court's statements in a case that did not involve epidemiology. Specifically, the R&R cited *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296 (11th Cir. 2014), which approved a district court's determination that certain expert causation opinions suffered from

[7] To be sure, a poorly designed study might compare exposed and unexposed populations that are dissimilar in ways that affect the groups' respective background risks. *See Ref. Guide Epidem.* at 556 (cautioning against designing a study that creates "the possibility of differences in the two populations being studied with regard to risk factors other than exposure to the agent" under study). The R&R, however, did not suggest that its criticism regarding background risk pertained to study design.

"serious methodological deficienc[ies]" because they failed to account for the background risk of the health condition under consideration. *Id.* at 1307 (citation omitted); R&R at 35. But the experts in *Chapman* offered "no analytical epidemiological evidence on which to base their inference[s] of causation," 766 F.3d at 1307 (citation omitted), instead relying largely on "generalized case reports" about people who had used a particular consumer product and experienced the condition, *id.* at 1308.

In the context of "anecdotal evidence such as case reports," *Rider*, 295 F.3d at 1199, an expert's lack of information about background risk is consequential. Without such information, an expert has no basis for concluding that "symptoms observed in a single patient in an uncontrolled context" are evidence of a causal association rather than an "idiosyncratic" happenstance. *Id.* By contrast, the whole point of an epidemiological study is to identify an association between a population-wide exposure to a particular substance and an increased incidence of a particular health condition, as compared to the incidence within an

unexposed comparator group. Unlike *Chapman*'s case-study approach, then, epidemiology by its very nature incorporates background risk.[8]

4. Finally, the R&R faulted Dr. Freeman for discussing crude oil and dispersants generally instead of identifying which precise chemicals may have triggered Plaintiffs' health conditions. R&R at 54. The R&R cited no scientific authority suggesting that a reliable epidemiological approach requires a researcher to identify specific chemicals within a composite substance that is associated with an adverse health outcome. Indeed, doing so would typically require the sort of laboratory conditions that characterize toxicology, not epidemiology. Given that observational epidemiology examines real-world situations, it is hardly unusual—let alone unreliable—for an epidemiologist to assess the health impact of being exposed to a substance in the form in which it generally actually appears. *Cf. Ref. Guide Epidem.* at 606 (rejecting cigarette manufacturers' claims that the high number of health effects linked to

[8] In connection with its exclusion of an expert opinion not at issue here, the R&R also briefly suggested that background risk is relevant to "whether the Plaintiffs could have suffered from [health conditions] based on other sources." R&R at 50. This point goes to the question of *specific* causation—*i.e.*, whether exposure to crude oil and dispersants caused *Plaintiffs'* conditions. It does not go to general causation—*i.e.*, whether such exposure can ever be capable of causing such conditions.

smoking undermines an inference of causation and observing that "tobacco and cigarette smoke are not in fact single agents but consist of numerous harmful agents … with multiple possible effects").

CONCLUSION

This Court should reverse the district court's judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B)(i) because, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and the Rules of this Court, it contains 5,758 words.

This brief also complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 29(a)(4), 32(a)(5), and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief of Amicus Curiae with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit on September 21, 2023, using the Appellate Electronic Filing system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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